AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (currently Amended) A process for producing parenterally administrable microparticles containing a biologically active substance, which process comprises:

a) preparing an aqueous solution of the biologically active substance to be incorporated in the microparticles,

b) ~~concentrating the biologically active substance into a highly viscous solution thereof, which has the ability of forming droplets which can be handled at room temperature or into a precipitation thereof in the form of solid particles by~~ mixing the solution obtained in step a) with an aqueous solution of polyethylene glycol to form a concentrated solution or solid particle precipitate of the biologically active substance,

c) optionally washing the concentrated biologically active substance obtained in step b),

d) mixing the concentrated biologically active substance obtained in step b) or c) with an aqueous starch solution,

e) mixing the composition obtained in step d) with an aqueous solution of a polymer having the ability of forming a two-phase aqueous system, so as to form an emulsion of starch droplets which contain the biologically active substance as the inner phase in an outer phase of said polymer solution,

f) causing or allowing the starch droplets obtained in step e) to solidify into starch microparticles,

g) drying the starch microparticles from step f), and

h) optionally applying a release controlling shell of a biocompatible and biodegradable polymer to the dried starch microparticles from step f).

Claim 2. (currently amended) A process according to claim 1, in which step b) is performed such that ~~the solidification of~~ the biologically active substance ~~leads to precipitation of the same~~ precipitates from the aqueous solution obtained in step a) to form solid particles.

Claim 3. (currently amended) A process according to claim 1, in which step b) is performed such that ~~the solidification~~ a concentrated solution of the biologically active substance is formed ~~results in a highly viscous solution, which has~~ wherein the concentration solution has a viscosity that differs from the viscosity of the solution obtained step a) and the ability ~~of forming~~ to form droplets which can be handled at room temperature.

Claim 4. (Original) A process according to claim 1, in which step b) is performed to a reversibly solidified active substance.

Claim 5. (currently amended) A process according to claim 1, in which the ~~solidified~~ concentrated solution of biologically active substance forms a pellet or a ~~highly viscous~~ solution of higher viscosity than the concentrated solution or solid bottom phase in centrifugation or ultracentrifugation.

Claim 6. (Original) A process according to claim 1, in which the polyethylene glycol used in step b) has an average molecular weight of 400-100,000 Da, preferably 4 000-35000 Da, more preferably 6 000-20,000 Da, and most preferably about 20,000 Da.

Claim 7. (previously presented) A process according to claim 1, in which the concentration of the polyethylene glycol used in step b) is in the range of 1-50 % (w/w).

Claim 8. (Original) A process according to claim 1, in which step d) an aqueous starch solution is utilized, comprising starch which has an amylopectin content exceeding 85 % by weight, in which the molecular weight of the said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 10-10 000 kDa.

Claim 9. (Original) A process according to claim 1, in which step d) an aqueous starch solution is utilized, comprising starch which has an amino acid nitrogen content of less than 50 μg per g dry weight of starch.

Claim 10. (Original) A process according to claim 1, in which the starch concentration of the aqueous starch solution used in step d) is at least 20 % by weight.

Claim 11. (previously presented) A process according to claim 8, in which the starch has a purity of at most 20 μg amino acid nitrogen per g dry weight of starch.

Claim 12. (previously presented) A process according to claim 8, in which the starch has an amylopectin content with said reduced molecular weight exceeding 95 % by weight.

Claim 13. (previously presented) A process according to claim 8, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 100-4000 kDa.

Claim 14. (Original) A process according to claim 1, in which the starch is such that it can only be dissolved to a concentration exceeding 25 % by weight in water.

Claim 15. (previously presented) A process according to claim 1, in which the starch lacks covalently bonded extra chemical groups which are found in hydroxyethyl starch.

Claim 16. (Original) A process according to claim 1, in which the starch has an endotoxin content of less than 25 EU/g and contains less than 100 microorganisms per g.

Claim 17. (Original) A process according to claim 1, in which the starch is essentially purified from surface-located proteins, lipids and endotoxins by means of washing with an aqueous alkali solution and purified from internal proteins by means of ion-exchange chromatography, preferably anion-exchange chromatography.

Claim 18. (previously presented) A process according to claim 8, in which in step d) 215 % by weight amylose is also used as starch, having an average molecular weight within the range of 2.5-70 kDa in which the percentage by weight is calculated on the basis of dry weight starch.

Claim 19. (Original) A process according to claim 8, in which in step d) a solution is prepared having a starch concentration of at least 30% by weight.

Claim 20. (previously presented) A process according to claim 8, in which in step d) a solution is prepared having a starch concentration of at most 50% by weight.

Claim 21. (Original) A process according to claim 8, in which the aqueous starch solution in step d) is prepared with accompanying autoclaving.

Claim 22. (previously presented) A process according to claim 1, in which in step d) the active substance is combined with the starch solution at a temperature of at most 60°C

Claim 23. (Original) A process according to claim 1, in which in step d) a composition is formed in which the weight ratio between starch and biologically active substance lies within the range of 3:1 to 10 000:1.

Claim 24. (previously presented) A process according to claim 1, in which the mixing in step e) is performed at a temperature within the range of 4-50°C.

Claim 25. (Original) A process according to claim 1, in which the mixing in step e) is performed by means of at least one static mixer.

Claim 26. (Original) A process according to claim 1, in which in step e) the polymer solution is added to the composition in at least two steps, at least one of the additions being effected after the emulsion has begun to be created.

Claim 27. (Original) A process according to claim 1, in which in step e) polyethylene glycol is used as the aqueous polymer.

Claim 28. (previously presented) A process according to claim 27, in which the polyethylene glycol has an average molecular weight of 5-35 kDa.

Claim 29. (previously presented) A process according to claim 1, in which in step e) starch droplets are formed which give the size required for the microparticles, in the dry state, within the range of 10-200 gm,.

Claim 30. (Original) A process according to claim 29, in which after step e) the microparticles are washed, through filtration, and optionally sieved in order to obtain the desired particle size distribution.

Claim 31. (Original) A process according to claim 1, in which the solidification in step f) is effected at at least two temperatures, in which the initiation is effected at a lower temperature than the termination.

Claim 32. (previously presented) A process according to claim 31, in which the solidification is initiated within the range of 1-20°C, and is terminated within the range of 2055°C.

Claim 33. (previously presented) A process according to claim 1, in which the drying in step g) is performed in the form of spray-drying, freeze-drying or vacuum-drying.

Claim 34. (previously presented) A process according to claim 1, in which, as the biologically active substance, a substance is incorporate which is selected from the group consisting of proteins, peptides, polypeptides, polynucleotides and polysaccharides

Claim 35. (Original) A process according to claim 1, in which the application of the release-controlling shell in step h) is performed by means of air suspension technology.

Claim 36. (Original) A process according to claim 1, in which the release-controlling shell in step h) is formed by a homopolymer of copolymer containing alpha-hydroxy acid units.

Claim 37. (Original) A process according to claim 36, in which the alpha-hydroxy acid is lactic acid and/or glycolic acid.

Claim 38. (Withdrawn) Microparticles suitable for parenteral administration, preferably via injection, to a mammal, especially a human being, and containing a biologically active substance, which microparticles essentially consist of parenterally

administrable, biodegradable starch as a matrix, which contains the biologically active substance in essentially non-chemically complex bonded form and in the form of solid particles having a mean size within the range of 0.05-30 μm.

Claim 39. (Withdrawn) Microparticles according to claim 38, in which the biologically active substance is a precipitated substance.

Claim 40. (Withdrawn) Microparticles according to claim 38, in which the particles of the biologically active substance have a mean size within the range of 0.2-10 μm, preferably 0.5-5 gm, more preferably 1-4 μm.

Claim 41. (Withdrawn) Microparticles according claim 38, in which the starch has an amylopectin content exceeding 85% by weight, of which at least 80% by weight has an average molecular weight within the range of 10-1000 kDa.

Claim 42. (Withdrawn) Microparticles according to claim 38, in which the starch has an amino acid nitrogen content of less than 50 μg per g dry weight starch and which microparticles have no covalent chemical cross-linking between the starch molecules.

Claim 43. (Canceled)

Claim 44. (Withdrawn) Microparticles according to claim 138, which have a release-controlling shell obtained or formed according to claim 35.

Claim 45. (Canceled)

Claim 46. (Withdrawn) Microparticles according to claim 38, which are biodegradable in vitro in the presence of alpha-amylase and/or amyloglucosidase.

Claim 47. (Withdrawn) Microparticles according to claim 38, which are biodegradable and are eliminated from tissue after subcutaneous or intramuscular administration.

Claim 48. (Withdrawn) Microparticles according to claim 38, in which the biologically active substance is chosen from the group consisting of proteins, peptides, polypeptides, polynucleotides and polysaccharides.

Claim 49. (Withdrawn) Microparticles according to claim 48, in which the protein is a recombinantly produced protein.

Claim 50. (Withdrawn) Microparticles according to claim 48, in which the protein is chosen from amongst growth hormones, colony-stimulating factors, erythropoietins, interferons, insulin and vaccines.

Claim 51. (Withdrawn) Microparticles according to claim 50, in which the protein is a growth hormone.

Claim 52. (Withdrawn) Microparticles according to claim 51, in which the growth hormone is human growth hormone (hGH).

Claim 53. (Withdrawn) Microparticles according to claim 38, in which the divalent metal ions content is such that the molecular ratio of total metal cations; biologically active substance is less than 0.2:1, preferably less than 0.1:1, more preferably less than 0.01:1.

Claim 54. (Withdrawn) Microparticles according to claim 53, in which the quoted molecular ratios apply to zinc as the said metal.

Claim 55. (Withdrawn) Microparticles according to claim 52, in which the dimers content of the human growth hormone is <2% by weight, preferably <1% by weight and the polymers content is <0.2% by weight, preferably <0.1% by weight.

Claim 56. (Withdrawn) Microparticles according to claim 52, in which the release kinetics for hGH determined in vitro are characterized by substantially continuous and regular release over one week.

Claim 57. (Withdrawn) Microparticles which are obtainable by means of a process according to any one of claim 1.

Claim 58. (Withdrawn) Microparticles suitable for parenteral administration, preferably via injection, to a mammal, especially a human being, and containing a biologically active substance, which microparticles essentially consist of parenterally administrable, biodegradable starch as a matrix, which contains the biologically active substance in essentially non-chemically complex-bonded form and in the form of solid particles having a mean size within the range of 0.05-30 μm in which the starch is of the kind defined in claim 6.

Claim 59. (Withdrawn) Microparticles suitable for parenteral administration, preferably via injection, to a mammal, especially a human being, and containing a biologically active substance, which microparticles essentially consist of parenterally administrable, biodegradable starch as a matrix, which contains the biologically active substance in essentially non-chemically complex-bonded form and in the form of solid particles having a mean size within the range of 0.05-30 μm which have a release-controlling shell obtained or formed according to claim 35.

Claim 60. (previously presented) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 2-45 % (w/w).

Claim 61. (previously presented) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 10-40 % (w/w).

Claim 62. (previously presented) The process according to claim 7, in which the concentration of the polyethylene glycol used in step b) is in the range of 20-30 % (w/w).

Claim 63. (previously presented) The process according to claim 11, in which the starch has a purity of at most 10 μg amino acid nitrogen per g dry weight of starch.

Claim 64. (previously presented) The process according to claim 11, in which the starch has a purity of at most 5 μg amino acid nitrogen per g dry weight of starch.

Claim 65. (previously presented) The process according to claim 12, in which the starch has an amylopectin content with said reduced molecular weight exceeding 98 % by weight.

Claim 66. (previously presented) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80 % by weight of the material lies within the range of 200- 1000 kDa.

Claim 67. (previously presented) The process according to claim 13, in which the molecular weight of said amylopectin has been reduced such that at least 80% by weight of the material lies within the range of 300-600 kDa.

Claim 68. (previously presented) The process according to claim 18, in which in step d) 215 % by weight amylose is also used as starch, having an average molecular weight within the range of 5-45 kDa in which the percentage by weight is calculated on the basis of dry weight starch.

Claim 69. (previously presented) The process according to claim 20, in which in step d) a solution is prepared having a starch concentration of at most 45 % by weight.

Claim 70. (previously presented) The process according to claim 22, in which in step d) the active substance is combined with the starch solution at a temperature of 20-45°C.

Claim 71. (previously presented) The process according to claim 22, in which in step d) the active substance is combined with the starch solution at a temperature of 30-37°C.

Claim 72. (previously presented) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-40°C.

Claim 73. (previously presented) The process according to claim 24, in which the mixing in step e) is performed at a temperature within the range of 10-37°C.

Claim 74. (previously presented) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of 15-25 kDa.

Claim 75. (previously presented) The process according to claim 28, in which the polyethylene glycol has an average molecular weight of ca. 20 kDa.

Claim 76. (previously presented) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles as a mean particle diameter.

Claim 77. (previously presented) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles in the dry state, within the range of 20-100 4m.

Claim 78. (previously presented) The process according to claim 29, in which in step e) starch droplets are formed which give the size required for the microparticles in the dry state, within the range of 20-80 /.cm.

Claim 79. (previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-10°C, and is terminated within the range of 2055°C.

Claim 80. (previously presented) The process according to claim 32, in which the solidification is initiated around 4°C, and is terminated within the range of 20-55°C.

Claim 81. (previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated within the range of 20-40^{0}C.

Claim 82. (previously presented) The process according to claim 32, in which the solidification is initiated within the range of 1-20°C, and is terminated around 37°C.

Claim 83. (previously presented) The process according to claim 33, in which the drying in step g) is performed in the form of freeze-drying.

Claim 84. (previously presented) The process according to claim 34, wherein the protein is a recombinantly produced protein.